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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/138,735	08/24/1998	GLAUCIA PARANHOS-BACCALA	WPB-36400B	4465
25944	7590	10/03/2003		
OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320				
EXAMINER NAVARRO, ALBERT MARK				
ART UNIT		PAPER NUMBER		
1645		33		
DATE MAILED: 10/03/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
**09/138,735**

Applicant(s)  
**Baccala et al**

Examiner  
**Mark Navarro**

Art Unit  
**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Sep 8, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Sep 8, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s):

See attached

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: \_\_\_\_\_

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

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### ADVISORY ACTION

Applicants amendment filed September 8, 2003 (Paper Number 32) has been received and entered. Consequently, claims 1, 2, 5, 7, 8, 10-27, 32, 34, and 36-42 are pending in the instant application.

#### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 5, 7, 8, 10-26, 32, 34, and 36-42 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants are asserting that claim 27 does not contain “consists essentially of” language or “% homology” language. Applicants arguments are persuasive and this rejection has been withdrawn from claim 27.

Applicants further assert that claims 21-23 have been amended to delete the term “essentially.” Applicants further assert that claims 5 and 8 are directed to probes and primers that “consist essentially of” language which does not render the claimed non-enabled. Applicants further assert that one of ordinary skill in the art is well aware that additional matter can be added to a probe or primer without affecting the basic and novel characteristics of that probe or primer. Applicants report that “it is well known in the art that additional nucleotides can be added to one

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or more ends of a probe or primer without affecting the basic and novel characteristics of that probe or primer.” Applicants further assert that it is clear from the claims and specification that the basic and novel characteristics of the inventions of claims 5 and 8 are clearly the ability of these sequences to hybridize and therefore act as a probe or primer, respectively, for identifying *Trypanosoma cruzi* or amplifying a nucleotide sequence thereof.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claims 21-23 have been amended to delete the term “essentially.” However, the claims are non-enabled for “consisting essentially” language as well as “85% identity” language. Claims 21-23 all recite the limitation of “85% identity” and as such are properly included within this rejection. As set forth previously, DNA consists of 4 distinct nucleotides which bind in pairs of adenine (A) = thymine (T) and guanine (G) = cytosine (C). Changing any one of these nucleotides (as permitted by 85% homology) results in a probe/primer which will now bind to other molecules of unknown function and unknown origin.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands,

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858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999).

Applicants specification does not provide any working examples of DNA probes/primers having 85% identity to SEQ ID NO: 1. Furthermore, as set forth above, the unpredictability of randomly altering nucleotides creates uncertainty as to what DNA molecules will now hybridize to the probe. For instance, given that there are 4 nucleotides contained within DNA, and Applicants probes can be as short as 5 nucleotides, every  $(4)^5$  or 1 in 1024 nucleotides will contain an exact 5 nucleotide match. This number grows larger when factoring in the 85% homology limitations. Given that the human genome has approximately 2,900,000,000 nucleotides, Applicants "probes" will be hybridizing to a lot of DNA molecules. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

Applicants further assert that "it is well known in the art that additional nucleotides can be added to one or more ends of a probe or primer without affecting the basic and novel characteristics of that probe or primer." However, Applicants have offered no evidence to support those sweeping conclusion. As demonstrated above by DNA binding interactions,

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changing even a single base, or adding additional bases 5 primed or 3 primed will have a pronounced impact on molecules which will be capable of undergoing hybridization.

Finally, Applicants assert that it is clear from the claims and specification that the basic and novel characteristics of the inventions of claims 5 and 8 are clearly the ability of these sequences to hybridize and therefore act as a probe or primer, respectively, for identifying *Trypanosoma cruzi* or amplifying a nucleotide sequence thereof. However, this still does not address the issue of the rejection. Changing nucleotides within a sequence or adding additional nucleotides upstream or downstream exerts a profound impact on the activity of that probe. These changes are simply unpredictable as set forth in the Wands analysis.

For reasons of record in Paper Number 27, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-42 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants are asserting that claims 21-23 and 27 do not recite “consists essentially of” language. Applicants further argue that although the Federal Circuit has held that merely reciting an invention does not necessarily provide written description for that invention, the present

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specification, which recites SEQ ID NO: 1, clearly provides written description for claims 5 and 8.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants assert that claims 21-23 and 27 do not recite “consists essentially of” language. However, as set forth previously, the specification discloses a single example, SEQ ID NO: 1. Description of other examples which meet the requirement of the genus claim (85%) are lacking. Consequently, Applicants sole described examples are limited to SEQ ID NO: 1 or fragments “consisting of” SEQ ID NO: 1. Furthermore, in regards to claim 27. Applicants “probe” does not recite any structure requirements. This simply leaves one of skill in the art to try to figure out what sequence of nucleotides, what length, what conditions of hybridization must be employed to practice the claim. The written description requirement is simply not satisfied.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

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For reasons of record in Paper Number 27, as well as the reasons set forth above, this rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 5, 8, 10-11, 17, 25-26, 32, 34, 39 and 40 under 35 U.S.C. 102(b) as being anticipated by Birkett *et al* is maintained.

Applicants are asserting that the inherency law “must be a necessary result and not merely a possible result.” The mere fact that a certain thing may result from a given set of circumstances is not enough. *In re Oelrich* 666 F.2d 578,581, 212 USPQ 323, 326 (CCPA 1981).

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants appear to be under the impression that the random hexamer probes disclosed by Birkett et al will not necessarily hybridize to SEQ ID NO: 1 of the instant invention.

Applicants are respectfully directed to their own specification, page 23, in which random hexamer probes (the same kind of probes disclosed by Birkett et al) were used to synthesize SEQ ID NO:



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1 of the instant invention. Applicants "necessary result" is supported by Applicants own specification.

Since the Patent office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The claims are drawn to isolated probe which is identical or fully complementary to nucleotides 1232-2207 of SEQ ID NO: 1, wherein said probe contains at least 5 and no more than 100 nucleotides.

Birkett *et al* (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that the isolated hexamer oligonucleotide primers contain every possible nucleotide sequence of six consecutive nucleotides, and that these sequences will inherently match those of SEQ ID NO: 1, the disclosure of the hexamer kit by Birkett *et al* is seen to anticipate the claimed invention.

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***Claim Rejections - 35 USC § 112***

4. The rejection of claims 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is withdrawn.

Claims 1-2 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

October 1, 2003